

REMARKS

Claims 1-41 are pending with claims 18, 19, 21, 22, 27, and 31-41 under examination. Applicants have amended claims 18 and 32 to indicate that administering an effective amount of Galectin-1 to the brain enhances proliferation of neural stem cells. Applicants have also amended claims 21 and 36 to indicate that administering an effective amount of Galectin-1 to the brain enhances proliferation of SVZ astrocytes. The specification supports these amendments at, for example, paragraphs [0019], [0020], [0022], [0023], [0046], and [0048] of published application number 2007/098701 A1. Thus, these amendments do not add new matter.

Claims 18, 19, 21, 22, 27, and 31-41 are rejected under one or more of 35 U.S.C. §§ 103(a) and 112, second paragraph. Applicants address these rejections below.

Rejections Under 35 U.S.C. § 103

The Office rejects claims 18, 19, 27, and 31-35 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent 6,890,531 ("Horie"). Office Action, page 3. According to the Office, Horie teaches "a method for treating widely divergent neurological disorders including neurodegenerative diseases such as neuropathy and nerve injury resulting from ischemia." *Id.* Horie also allegedly teaches "treatment of nerve damage resulting from **central and peripheral** nerve injuries . . . comprising treatment of degenerating nerve tissue . . . and promoting the regeneration of neurites." *Id.*, emphasis in original. The Office also relies on Horie's alleged teaching of the "treatment of neuropathies of central nerves . . . wherein administration of galectin-1, contained in collagen, for example, is directly embedded in to the neurological location

for treatment" and mutant galectin-1 polypeptide "in which a cys at position 2 was converted to ser." *Id.* at 4.

Acknowledging that Horie does not teach administration of Galectin-1 to the brain, the Office nonetheless concludes that this reference implicitly teaches this element by teaching administration of Galectin-1 directly to the central nerves. The Office also contends that "proliferation of neuronal stem cells would reasonably be expected as . . . Horie clearly discloses the same step of the claimed methods, i.e., administration of Galectin-1 to the brain in the vicinity of the neuronal stem cells." *Id.* at 5. "As neuronal stem cells are located in the brain," the Office reasons, "there would have been a reasonable expectation of success that administration of Galectin-1 [sic] . . . implicitly would regulate brain processes associated with stem cell proliferation." *Id.* Applicants traverse.

When responding to Applicants' prior arguments, the Office notes that "the instant claims do not place any limitation on the resulting functionality of administering Galectin-1 to the vicinity of neuronal stem cells." *Id.* at 6. Likewise, in its rejection, the Office also noted that claims 18 and 32 did not contain "any physical or structural property [in] the method of administration (e.g., wherein administration of the therapeutically effective amount of Galectin-1 [sic] increases proliferation of a neuronal stem cell)." *Id.* at 5. Solely to advance prosecution, Applicants have amended independent claims 18 and 32 to indicate that administration of Galectin-1 enhances proliferation of neural stem cells. Horie does not expressly or implicitly teach administering Galectin-1 to the brain in such a way as to enhance proliferation of neural stem cells. And, as the Office has agreed, "obviousness cannot be predicted on what is

not known at the time an invention was made, even if the inherency of a certain feature is later established." *Id.* at 6. Applicants therefore request that the Office withdraw this rejection.

Claims 21, 22, 36, and 37 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Horie as applied above and in further view of U.S. Patent 6,436,389 ("Gage") or Taupin et al., *Neuron* 28:385-97 (2000); ("Taupin"). *Id.* at 7. Applying Horie as discussed above, the Office notes that this reference does not teach "*in vivo* proliferation of a subventricular region (SVZ) astrocyte." *Id.* Gage allegedly discloses a method of treating neurodegenerative disorders comprising injection of adult hippocampus-derived neuronal progenitor cells ("AHPs") into the rat hippocampus. *See Id.* Gage also allegedly teaches "that intracerebral administration of FGF-2 has been shown to stimulate neurogenesis in the adult rat subventricular region of the brain." *Id.* Taupin, the Office contends, also teaches cell division in the rat subgranular layer and SVZ after injection of modified AHPs into the rat hippocampus. *See Id.*

Combining the alleged teachings of Horie and the alleged teachings of Gage and Taupin on the SVZ as an active neurogenetic area of the brain, the Office concludes that one of ordinary skill in the art would have recognized that treatment of cerebral ischemia and neural degenerative disease by administering Galectin-1 implicitly involved regeneration and remyelination of nerve injuries. Thus, the Office concludes, "it would have been *prima facie* obvious . . . to administer Galectin-1 to any brain region with the contemplated treatment of a neurological disorder . . . to stimulate neurogenesis in the subventricular region of the brain because this region is a rich neurogenic area." *Id.* at 8. Applicants traverse.

The Office again notes that the rejected claims, in this case claims 21 and 36, do not impart “any physical or structural property to the method of administration (e.g., wherein administration of the therapeutically effective amount of Galectin-1 [sic] increases proliferation of a SVZ astrocyte).” *Id.* Solely to advance prosecution, Applicants have amended independent claims 21 and 36 to indicate that administration of an effective amount of Galectin-1 enhances proliferation of SVZ astrocytes. Neither Horie, Gage, nor Taupin, alone or in combination, teach administering Galectin-1 to the brain in such a way as to enhance the proliferation of SVZ astrocytes. Applicants therefore request that the Office withdraw this rejection.

The Office rejects claims 18, 21, 32, 36, and 38-41 under 35 U.S.C. § 103(a) as allegedly obvious over Horie in view of Johansson *et al.*, *Exp. Cell Res.* 253:733-36 (1999); (“Johansson”). *Id.* at 10. Responding to Applicants' prior arguments, the Office contends that “administration of Galectin-1 at the site of the nerve injury to the central nerves implicitly requires administration to the brain.” *Id.* at 11. As such, the Office concludes, “any administration of Galectin-1 for treatment of neuropathies of central nerves as taught by Horie inherently would be expected to regulate stem cell proliferation [and] SVZ astrocyte proliferation.” *Id.* Applicants respectfully remind the Office, however, that obviousness cannot be predicated on inherency, an issue that the Office has noted and agree with. In addition, where Applicants previously argued that there was no teaching that administering Galectin-1 could enhance cell proliferation, the Office again noted that claims 21 and 36 did not contain any physical or structural property to the method of administration. *Id.* To advance prosecution, Applicants have amended claims 21 and 36 to indicate that administration of an effective amount of

Galectin-1 enhances proliferation of SVZ astrocytes. Horie does not teach administering Galectin-1 in such a way as to enhance the proliferation of neural stem cells or SVZ astrocytes. Adding Johansson, an apparent general tutorial on neuronal stem cells, cannot compensate for the absence of teaching in Horie. Applicants therefore request that the Office withdraw this rejection.

Rejections Under 35 U.S.C. § 112

Claims 18, 19, 21, 22, and 31-41 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the phrase “administering Galectin-1 to the vicinity of the neuronal stem cells.” *Id.* at 12. Specifically, the Office argues that the term “vicinity” is a relative term that is not defined by the specification. *See id.*

Solely to advance prosecution, Applicants amended independent claims 18, 21, 32, and 36 to recite “administering an effective amount of Galectin-1 to the brain.” As the language that the Office objects to is no longer in the claims, Applicants request that this rejection be withdrawn.

Applicants note that, despite this rejection, the Office arrived at its own definition of the term “vicinity.” *See id.* at 2 and 3. While Applicants do not necessarily agree with the Office’s analysis of this term, the issue has been rendered moot by the claim amendments submitted herewith.

The Office also contends that claims 18, 21, 32, and 36 are incomplete for allegedly omitting essential steps. According to the Office, “it is not apparent under what structural or functional parameters administration of Galectin-1 . . . is indicative or correlative to the preamble of the claims.” *Id.* at 13. As noted above, Applicants have amended claims 18, 21, 32, and 36 to indicate that administration of Galectin-1

enhances proliferation of neural stem cells or SVZ astrocytes. As such, the claims as amended recite a functional parameter as requested by the Office.

Finally, the Office also contends, with respect to claims 18, 21, 32, and 36, that it is not clear how administration of Galectin-1 enhances proliferation of merely one SVZ astrocyte or one neural stem cell. Solely to advance prosecution, Applicants amended claims 18 and 32 to recite "neural stem cells" and claims 21 and 36 to recite "SVZ astrocytes."

As Applicants' amendments have rendered this rejection moot, Applicants request that the Office withdraw it.

Conclusions

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of claims 18, 19, 21, 22, 27, and 31-41.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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